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EXAMINER
STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/076,416	RIEPING ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,25-28,30,33 and 35-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,25-28,30,33 and 35-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 23, 25-28, 30, 33, and 35-43 are pending in the application.

[2] Applicant's amendment to the claims, filed on 2/23/07, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Applicant's arguments filed on 2/23/07 in response to the Office action mailed on 7/25/06 are acknowledged. Applicant's arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[4] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

[5] Claim(s) 23, 25-28, 30, 33, and 35-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claim 23 (claims 25-28, 30, 33, and 39-43 dependent therefrom) is confusing in the recitation of "an inactivated poxB gene which encodes a pyruvate oxidase," because it is unclear as to how an "inactivated poxB gene" can encode a functional pyruvate oxidase. According to applicant, "[t]he requirement that poxB is inactivated clearly means that the polypeptide is not functional" (instant response at p. 8, bottom).

However, there is no such requirement in the claim and MPEP 2111.01.II makes clear that "it is important not to import into a claim limitations that are not part of the claim." It is suggested that applicant clarify the meaning of the noted phrase.

[b] Claim 23 (claims 25-28, 30, 33, and 35-43 dependent therefrom) recites the active method step of "concentrating the L-amino acid…from the Escherichia cells," which would appear to have the intended meaning of concentrating L-amino acids obtained from the cells. However, this is confusing as a subsequent active method step recites "isolating said L-amino acid…from the Escherichia cells." It is suggested that applicant clarify the meaning of the noted phrase.

[c] Claim 23 (claims 25-28, 30, 33, and 39-43 dependent therefrom) is indefinite in the recitation of "the poxB gene is obtainable by PCR amplification using SEQ ID NO:5 and SEQ ID NO:8." First, it is noted that the "poxB gene obtainable" by PCR is relative to the DNA that is amplified and the conditions used for amplification. It is well-known in the prior art that a nucleic acid that is amplified by PCR under certain conditions will not necessarily be amplified under other PCR conditions. Alternatively, under certain conditions, a plurality of structurally distinct nucleic acids can be obtained by PCR amplification due to non-specific annealing of primers to a nucleic acid template. See Rychlik et al. (*Nuc Acids Res* 18:6409-6412), which teaches that under sub-optimal annealing temperatures, "non-specific products were formed" during a PCR amplification reaction. Further, it is noted that SEQ ID NO:5 and 8 are used in the amplification to obtain "the poxB gene." Is the recited "poxB gene obtainable by PCR amplification" intended as being the inactivated poxB gene or poxB gene prior to

inactivation? Also, it is noted that, according to the specification, SEQ ID NO:5 and 8 appear to be used for amplification of 5'- and 3'-deletion fragments of SEQ ID NO:1 (Example 1 at pp. 13-14 of the specification) and not for amplification of a poxB gene. It is suggested that applicant clarify the meaning of the noted phrase.

Claim Rejections - 35 USC § 112, First Paragraph

[6] The new matter rejection of claim 30 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action.

RESPONSE TO ARGUMENT: Applicant argues the rejection is obviated by amendment to recite only the rhtC and gdhA polynucleotides from E. coli, pointing to pp. 17 and 19 as providing supporting disclosure for these limitations in the claim.

Applicant's argument is not found persuasive. Claim 30 is drawn to the process of claim 23, wherein the modified microorganism further comprises at least one overexpressed gene product encoded by an E. coli rhtC gene or an E. coli gdhA gene. While the disclosure at p. 17 would appear to support an E. coli K12 MG1655 gdhA gene having the nucleotide sequence as disclosed in GenBank Accession Numbers AE000270 and AE000271, applicant's cited disclosure would not appear to support the broader genus of any E. coli gdhA gene, from any E. coli strain. Similarly, while the disclosure at p. 17 would appear to support an E. coli K12 MG1655 rhtC gene having the nucleotide sequence as disclosed in GenBank Accession Number AE000458, applicant's cited disclosure would not appear to support the broader genus of any E. coli

rhtC gene, from any E. coli strain. Applicant is invited to show support for the limitations at issue.

[7] Claims 23, 25-28, 30, 33, and 35-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description."

Claim 23 (claims 25-28, 30, 33, and 35-43 dependent therefrom) has been amended to recite "concentrating the L-amino acid...from the Escherichia cells," which, as noted above, would appear to have the intended meaning of concentrating L-amino acids obtained from the cells. In view of this interpretation, the specification does not appear to provide descriptive support for the series of active method steps as recited in claim 23. Applicant is invited to show support the limitation at issue.

Claim 23 (claims 25-28, 30, 33, and 35-43 dependent therefrom) has been amended to recite "wherein the poxB gene is obtainable by PCR amplification using

SEQ ID NO:5 and SEQ ID NO:8." Applicant points to Example 1 at pp. 13-14 as showing support for the noted limitation. However, Example 1 would appear to support amplification of 5'- and 3'-deletion fragments of SEQ ID NO:1. Thus, applicant's cited disclosure would not appear to support the broad genus of any poxB gene from any source "obtainable by PCR amplification using SEQ ID NO:5 and SEQ ID NO:8." Applicant is invited to show support the limitation at issue.

[8] The written description rejection of claims 23, 25-28, 30, 33, and 39-41 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action. Upon further consideration, claims 42-43 are included in the instant rejection. Thus, claims 23, 25-28, 30, 33, and 39-43 are rejected.

RESPONSE TO ARGUMENT: Applicant argues the rejection is obviated to limit the genus of poxB genes to those that are "obtainable by PCR amplification using SEQ ID NO:5 and SEQ ID NO:8" and, in view of the specification's reference to a poxB GenBank Accession Number and the prior art, the genus of poxB genes is adequately described. According to applicant, the gene is identified by source, its encoded protein product, and a representative disclosed species of SEQ ID NO:1 and the inactivation of poxB enzymes is not the novel feature, rather the novel feature is the use of a cell having an inactivate poxB gene in the production of L-amino acids. Applicant argues the examiner's assertion that an inactivated poxB gene does not necessarily result in a non-functional polypeptide does not make sense.

Applicant's argument is not found persuasive. The examiner maintains the position that the single disclosed representative species of modified microorganisms, *i.e., Escherichia coli* comprising a chromosomal poxB gene inactivated by homologous recombination, wherein the poxB gene has the nucleotide sequence of SEQ ID NO:1, and the inactivated poxB gene encodes a non-functional poxB polypeptide, fails to reflect the variation among the members of the genus of modified microorganisms used in the claimed method.

According to MPEP 2163, "[a]n applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics" (citation omitted). In this case, the specification discloses a single species of the recited genus of modified bacteria, *i.e.,* an *Escherichia coli* comprising a poxB gene inactivated by homologous recombination, wherein the poxB gene has the nucleotide sequence of SEQ ID NO:1, and the inactivated poxB gene encodes a non-functional poxB polypeptide, wherein the specification discloses a correlation between inactivating the poxB gene of SEQ ID NO:1 as having the functional effect of encoding a non-functional pyruvate oxidase polypeptide. However, as noted above, the genus is not so limited, encompassing widely variant species including any *Escherichia* bacterium, which comprises an

inactivated poxB gene encoding a pyruvate oxidase polypeptide, wherein the poxB gene is obtainable by PCR amplification using SEQ ID NO:5 and 8.

There is no dispute that the nucleotide sequence of the *E. coli* K12 poxB gene was known in the art at the time of the invention. However, this single species fails to describe all members of the recited genus of poxB genes as encompassed by the claims. In this case, the genus of poxB genes encompasses any poxB gene that is "obtainable by PCR amplification using SEQ ID NO:5 and 8," which is not limited to an *Escherichia* source, but can be from any source. It is well-known in the prior art that a plurality of nucleic acids can be amplified from a single template due to non-specific annealing of primers. See, *e.g.,* Rychlik et al. (*Nuc Acids Res* 18:6409-6412), which teaches that under sub-optimal annealing temperatures, "non-specific products were formed" during a PCR amplification reaction. Also, it is well-known in the prior art that numerous mutations can be introduced into PCR-amplified DNA. See, *e.g.,* Keohavong et al. (*PNAS* 86:9253-9257). Even assuming *arguendo* the poxB gene was limited to SEQ ID NO:1, there is no requirement that inactivating the poxB gene results in an encoded non-functional polypeptide. While applicant argues "[t]he requirement that poxB gene is inactivated clearly means that the polypeptide is not functional" (instant response at p. 8, bottom), there is no such requirement in the claim and MPEP 2111.01 states "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow" and MPEP 2111.01.II makes clear that "it is important not to import into a claim limitations that are not part of the claim." Claim 23 recites, "an inactivated poxB gene encoding a pyruvate oxidase, wherein inactivation is achieved by...deletion

mutagenesis..." Thus, the claim has not been so narrowly interpreted as requiring a non-functional pyruvate oxidase, but has been broadly interpreted as encompassing deletion mutants, which maintain pyruvate oxidase activity. It is also noted that the poxB gene that is inactivated is not limited to being a chromosomal poxB gene, but can be an exogenous poxB gene incorporated into an expression vector.

Regarding claim 30, it is noted that it is not the structure of the genes that is at issue. Rather, it is the modification to the microorganism that results in the gene being overexpressed. In this case, the specification describes only a single representative species of microorganisms with an overexpressed *E. coli* rhtC and/or *E. coli* gdhA gene, *i.e.,* an *Escherichia* microorganism transformed with an expression vector encoding *E. coli* rhtC and/or *E. coli* gdhA gene. This single species fails to reflect the variation among the genus of modified microorganisms, particularly with respect to the modification(s) that result in overexpressed *E. coli* rhtC and/or *E. coli* gdhA gene.

Given the lack of description of a representative number of species, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[9] The scope of enablement rejection of claims 23, 25-28, 30, 33, and 39-41 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action. Upon further

consideration, claims 42-43 are included in the instant rejection. Thus, claims 23, 25-28, 30, 33, and 39-43 are rejected.

RESPONSE TO ARGUMENT: Applicant argues for reasons addressed in response to the written description rejection, there should be no issue regarding making and using the claimed invention.

Applicant's argument is not found persuasive. The examiner maintains the position that the specification fails to enable the full scope of the claimed invention. Regarding claim 23, the claim broadly encompass the use of any *Escherichia* microorganism that has an "inactivated poxB gene which encodes a pyruvate oxidase," wherein inactivation is achieved by the methods recited in claim 23. In this case, the scope of poxB genes encompasses any poxB gene that is "obtainable by PCR amplification using SEQ ID NO:5 and 8," which is not limited to an *Escherichia* source, but can be from any source. It is well-known in the prior art that a plurality of nucleic acids can be amplified from a single template due to non-specific annealing of primers. See, *e.g.*, Rychlik et al. (*Nuc Acids Res* 18:6409-6412), which teaches that under sub-optimal annealing temperatures, "non-specific products were formed" during a PCR amplification reaction. Also, it is well-known in the prior art that numerous mutations can be introduced into PCR-amplified DNA. See, *e.g.*, Keohavong et al. (*PNAS* 86:9253-9257). As noted above, there is no requirement that the "inactivated poxB gene which encodes a pyruvate oxidase" encode a non-functional polypeptide and the claim has been broadly interpreted as meaning that the *Escherichia* microorganism can have deletions of a poxB gene at the 5'- and/or 3'-ends, which are able to encode truncated

albeit functional poxB polypeptide. Even assuming *arguendo* the poxB gene was limited to SEQ ID NO:1, there is no requirement that inactivating the poxB gene results in an encoded non-functional polypeptide. While applicant argues "[t]he requirement that poxB gene is inactivated clearly means that the polypeptide is not functional" (instant response at p. 8, bottom), there is no such requirement in the claim and MPEP 2111.01 states "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow" and MPEP 2111.01.II makes clear that "it is important not to import into a claim limitations that are not part of the claim." Claim 23 recites, "an inactivated poxB gene encoding a pyruvate oxidase, wherein inactivation is achieved by...deletion mutagenesis..." Thus, the claim has not been so narrowly interpreted as requiring a non-functional pyruvate oxidase, but has been broadly interpreted as encompassing deletion mutants, which maintain pyruvate oxidase activity. It is also noted that the poxB gene that is inactivated is not limited to being a chromosomal poxB gene, but can be an exogenous poxB gene incorporated into an expression vector. Also, it is noted that claim 30 encompasses a modified *Escherichia* bacterium wherein *E. coli* rhtC and/or *E. coli* gdhA gene is overexpressed by any method or mechanism. In this case, the specification discloses only a single working example of the modified microorganisms, *i.e., Escherichia coli* comprising a chromosomal poxB gene inactivated by homologous recombination, wherein the poxB gene has the nucleotide sequence of SEQ ID NO:1, and the inactivated poxB gene encodes a non-functional poxB polypeptide, optionally wherein the bacterium is transformed with an expression vector encoding *E. coli* rhtC and/or *E. coli* gdhA gene. Other than this single working example, the specification fails

to provide guidance the use of SEQ ID NO:5 and 8 to obtain a poxB gene from any source and further fails to provide guidance regarding deletion mutants of any poxB gene encompassed by the claims. The disclosure of a single working example of modified microorganisms, *i.e., Escherichia coli* comprising an inactivated poxB gene, wherein the poxB gene has the nucleotide sequence of SEQ ID NO:1, and the inactivated poxB gene encodes a non-functional poxB polypeptide, is acknowledged. However, even among species of *Escherichia coli,* a plurality of different strains exists (specification at p. 4, top) and there is no evidence of record of a structural relationship among poxB genes of all species of the genus of *Escherichia* bacteria so that one could use the disclosed methods for inactivating the poxB genes in all *Escherichia* bacteria as encompassed by the claims. While methods of isolating homologous genes in related organisms were known in the art at the time of the invention, it was not routine in the art to isolate all poxB genes in all microorganisms of the *Escherichia* genus and to modify the corresponding microorganism to inactivate its poxB gene.

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability, and the amount of experimentation required, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance,

determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - Double Patenting

[10] The provisional obviousness-type double patenting rejection is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in the prior Office action.

RESPONSE TO ARGUMENT: Applicant argues the application in rejection part [c], [h], [o], [q], [w], and [z] are abandoned and [y] has issued as US Patent 7,052,883 and a terminal disclaimer has been filed. Applicant requests the remaining provisional rejections be held in abeyance with respect to the remaining applications.

Applicants' argument is not found persuasive. It is noted that the amendment filed on 10/25/06 – including a terminal disclaimer – was not entered for reasons set forth in the Office communication mailed on 1/24/07. The terminal disclaimer was not re-submitted in the amendment filed on 2/23/07. As to the remaining applications that are not abandoned, the provisional rejection is maintained.

[11] It is noted that because application 10/114,073 has now issued as US Patent 7,052,883, the rejection is no longer only a provisional rejection.

[12] The examiner reminds applicant that an earnest attempt has been made to identify those patents and/or co-pending applications for purposes of rejecting or

provisionally rejecting the claims for double patenting. However, it is noted that numerous co-pending applications have been filed and/or continue to be filed, and/or patents have issued disclosing subject matter that is related to the instant application. In the interest of compact prosecution, the examiner requests that: 1) applicants identify any patent(s) and/or co-pending application(s) that claim(s) subject matter that may necessitate a double patenting rejection, an obviousness-type double patenting rejection, a provisional double patenting rejection, or a provisional obviousness-type double patenting rejection; 2) identify the claims of the patents and/or co-pending applications that claim identical or similar subject matter; 3) identify the corresponding claims of the instant application, and 4) take the appropriate action, *e.g.*, cancel claims to preempt a statutory double patenting rejection and/or file a terminal disclaimer to preempt an obvious-type double patenting rejection or provisional rejection. Applicants' cooperation in following steps 1) to 4) above is appreciated as this will allow the examiner to focus on more substantive issues in the examination of the instant application.

Claim Rejections - 35 USC § 102/103

[13] The rejection of claim(s) 23-28, 33, 40, and 42-43 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chang et al. (*J Bacteriol* 154:756-762; cited in the Office action mailed on 10/19/2005) and the rejection of claim(s) 23-28, 33 and 41-43 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Grabau et

al. (*J Biol Chem* 264:12510-12519, 1989; cited in the IDS filed on 7/20/2004) are withdrawn in view of the amendment to claim 23 to require the active method step of "determining the concentration of the L-amino acids produced." The references of Chang et al. and Grabau et al. neither teach nor suggest such a step. As such, the references fail to teach all limitations of the claims and are thus not available as prior art under 35 U.S.C. 102.

Claim Rejections - 35 USC § 103

[14] The rejection of claim 39 under 35 U.S.C. 103(a) as being unpatentable over Grabau et al. (*supra*) in view of Yoder et al. (*DNA Cell Biol* 19:401-408, 2000) is withdrawn in view of the amendment to claim 23 as noted above to require the active method step of "determining the concentration of the L-amino acids produced."

Conclusion

[15] Status of the claims:

Claims 23, 25-28, 30, 33, and 35-43 are pending.

Claims 23, 25-28, 30, 33, and 35-43 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656